REMARKS

Upon entry of the above amendment, claims 1-16 and 18-20 will be pending in this application.

Neither the amendments to the claims nor the addition of new claims 19-20 introduce new matter within the meaning of 35 U.S.C. §132. Accordingly, the Examiner is respectfully requested to enter the above amendment before examination.

If the Examiner has any questions regarding this submission, she is invited to telephone the undersigned attorney.

Respectfully submitted,
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Appendix A

Claim Amendments

1. (Currently amended) ~~Pharmaceutical~~ A pharmaceutical composition ~~for the treatment of allergic rhinitis and/or allergic conjunctivitis~~ comprising as active ingredients a combination of at least one antihistamine, or a stereoisomer, a ~~Pharmaceutically~~ pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof,
and ciclesonide, or a pharmaceutically acceptable ~~salts~~ salt of ciclesonide, an ~~epimers~~ epimer of ciclesonide ~~optionally in any mixing ratio with ciclesonide~~, a ~~solvates~~ solvate of ciclesonide, a physiologically functional ~~derivatives~~ derivative of ciclesonide or a ~~solvates~~ solvate thereof,
and a pharmaceutically acceptable carrier and/or one or more excipients.

2. (Currently amended) ~~Pharmaceutical~~ The pharmaceutical composition according to claim 1 ~~for treatment of allergic rhinitis~~ for application to [[the]] mucosa, which is an aqueous pharmaceutical composition,

comprising the active ingredients together with one or more water-insoluble and/or water-low soluble ~~substance~~ substances, wherein said pharmaceutical composition has ~~and having~~ an osmotic pressure of less than 290 mOsm.

3. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said osmotic pressure is 150 mOsm or less.

4. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said osmotic pressure is 60 mOsm or less.

5. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said osmotic pressure is 40 mOsm or less.

6. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said osmotic pressure is 20 mOsm or less.

7. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, further comprising an osmotic pressure-controlling agent.

8. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said water-insoluble and/or water-low soluble substance is a cellulose.

9. (Original) The pharmaceutical composition for application to the mucosa according to claim 8, wherein said cellulose is microcrystalline cellulose.

10. (Currently amended) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said one or more water-insoluble and/or water-low soluble ~~substance~~ substances is/are present as solid particles in an aqueous medium.

11. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, further comprising a water-soluble polymer substance.

12. (Currently amended) ~~Pharmaceutical~~ The pharmaceutical composition for application to the mucosa according to claim 11, wherein a combination of said water-insoluble substance and water-soluble polymer is present which is microcrystalline cellulose and carboxymethyl cellulose sodium.

13. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, further comprising a surfactant and/or a wetting agent.

14. (Original) The pharmaceutical composition for application to the mucosa according to claim 2, wherein said mucosa is nasal mucosa.

15. (Currently amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~claims 1 through 14~~ claim 1, wherein the antihistamine is selected from the group consisting of (E)-6-[(E)-3-(1-pyrrolidinyl)-1-p-tolylpropenyl]-2-pyridineacrylic acid [INN:ACRIVASTINE], 6,11-Dihydro-11-(1-methyl-4-

piperidyliden)-5H-benzo[5,6]cyclohepta-[1,2-b]pyridin [INN:AZATADINE], 4-[(4-chlorophenyl)methyl]-2-(hexahydro-1-methyl-1H-azepin-4-yl)-1(2H)phthalazinone [INN:AZELASTINE], (+)-(S)-4-[4-[1-(4-chlorophenyl)-1-(2-pyridyl)methoxy]piperidin-1-yl]-butanoic acid [INN:BEPOTASTINE], (plus/minus)-[2-[4-(p-chloro-alpha-phenylbenzyl)-1-piperazinyl]ethoxy]-acetic acid [INN:CETIRIZINE], (+)-2-{2-[(p-Chlor-alpha-methyl-alpha phenylbenzyl)oxy]-ethyl}-1-methylpyrrolidin [INN:CLEMASTINE], 8-chloro-6,11-dihydro-11-(4-piperidylidene-5H-benzo[5,6]-cyclohepta-[1,2-b]pyridine [INN:DESLORATADINE], [3-(4-Chlorophenyl)-3-pyridin-2-yl-propyl]-dimethylamine [INN:DEXCHLORPHENIRAMINE], 4'-tert-butyl-4-[4-(diphenylmethoxy)-piperidino]butyrophenone [INN:EBASTINE], [2-[4-[bis(p-fluorophenyl)methyl]-1-piperazinyl]ethoxy]-acetic acid [INN:EFLETIRIZINE], 1-(2-ethoxyethyl)-2-hexahydro-4-methyl-1H-1,4-diazepin-1-yl)-benzimidazole [INN:EMEDASTINE], 3-amino-9,13b-dihydro-1H-dibenz[c,f]imidazo[1,5-a]azepine [INN:EPINASTINE], (plus/minus)-p-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)piperidino]-butyl]-alpha-methylhydratropic acid [INN:FEXOFENADINE], 3-[4-(8-

fluoro-5,11-dihydrobenz[b]oxepino[4,3-b]pyridin-11-ylidene)-piperidin-1-yl]propionic acid [Research Code HSR-609], (-)-(3S,4R)-1-[cis-4-cyano-4-(p-fluorophenyl)cyclohexyl]-3-methyl-4-phenylisonipecotic acid [INN:LEVOCABASTINE], [2-[4-[(R)-p-chloro-alpha-phenylbenzyl)-1-piperazinyl]ethoxy]-acetic acid [INN:LEVOCETIRIZINE], ethyl 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)-1-piperidinecarboxylate [INN:LORATADINE], 2[N-[1-(4-fluorobenzyl)-1H-benzimidazol-2-yl]-4-piperidinyl]-N-methyl-amino]pyrimidin-4(3H)-one [INN:MIZOLASTINE], 1-(4-fluorobenzyl)-2-(piperidin-4-ylamino)-1H-benzimidazole [INN:NORASTMIZOLE], 3-(10,11-dihydro-5H-dibenzo[a,d]cyclo-hepten-5-ylidene)-N-methyl-1-propanamine [INN:NORTRIPTYLINE], 9-methyl-3-(1H-tetrazol-5-yl)-4H-pyrido[1,2-a]pyrimidin-4-one [INN:PEMIROLAST], 8-chloro-11-[1-(5-methylpyridin-3-ylmethyl)-piperidin-4-ylidene]-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine [INN:RUPATADINE], 1-[2-[(p-chloro-alpha-methyl-alpha-phenylbenzyl)-oxy]ethyl]hexahydro-1H-azepine [INN:SETASTINE], S-(7-carboxy-4-hexyl-9-oxoxanthen-2-yl)-S-methylsulfoximine [INN:SUDEXANOX], 1-(p-tert-butyl-phenyl)-4-[4'-(alpha-

hydroxydiphenylmethyl)-1'-piperidyl]-butanol [INN:TERFENADINE], N-benzyl-N,N'-dimethyl-N-(2-pyridyl)-ethylenediamine [INN:TRIPELENAMINE], [[and]] 1-(4-fluorobenzyl)-2-(piperidin-4-ylamino)-1H-benzimidazole [INN:TECASTEMIZOLE], stereoisomers thereof, pharmaceutically acceptable salts thereof, ~~and/or~~ solvates thereof, and mixtures thereof.

16. (Currently amended) ~~Pharmaceutical~~ The pharmaceutical composition according to ~~claims 1 through 14~~ claim 1, wherein the antihistamine is selected from the group consisting of azelastine, levocabastine, ~~a salt or solvate~~ salts thereof and solvates thereof.

17. (Canceled)

18. (Currently amended) ~~Method~~ A method for the ~~prophylaxis or~~ treatment of allergic rhinitis and/or allergic conjunctivitis in a mammal, ~~such as a human,~~ which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising at least one antihistamine or a ~~pharmaceutical~~ pharmaceutically acceptable salt,

solvate, or physiologically functional derivative thereof,

and ciclesonide or a ~~pharmaceutical~~ pharmaceutically acceptable salt, solvate, or physiologically functional derivative thereof,

and a ~~pharmaceutical~~ pharmaceutically acceptable carrier and/or one or more excipients.

19. (New) The pharmaceutical composition according to claim 1, wherein said epimer of ciclesonide is present in any mixing ratio with ciclesonide.

20. (New) The method of claim 18, wherein said mammal is a human.

DT05 Rec'd PCT/PTO 18 FEB 2005

Appendix B

Abstract of the Disclosure

The present invention relates to a combination of ciclesonide with antihistamines.